

REMARKS

The application has been carefully reviewed in light of the Office Action dated August 14, 2002. Claims 1 to 6 and 8 to 14 are in the application, of which Claims 6 and 9 to 14 are withdrawn. Claims 1, 5, 9, 13 and 14 are independent claims.

Reconsideration and further examination are respectfully requested.

During a telephonic interview conducted on June 6, 2002, the Examiner informed the attorney responsible for the case that the application was being subject to a Restriction Requirement and one of four groups must be elected. In response, Group I, Claims 1 to 5, 7 and 8, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 1, vector, host cell and a process for producing a protein recombinantly, was elected, without traverse,. Applicants confirm the election of Group I, Claims 1 to 5, 7 and 8.

In the Office Action, Claims 1 to 5, 7 and 8 were rejected under 35 U.S.C. § 101 for alleged lack of utility. The same claims were also rejected under 35 U.S.C. § 112, first and second paragraphs. Finally, the same claims were rejected under 35 U.S.C. § 102 over Geneseq Accession NO: AAX60801 (Agostino) or, alternatively, over WO 99/26961 (Jacobs). Withdrawal of the rejections is respectfully requested.

Before addressing the rejections, Applicants wish to traverse the finding of priority in the Office Action. Parent Application 09/197,886 is seen to fully support the disclosure of clone bd306_7 and SEQ ID NO: 1 and SEQ ID NO:2. The disclosure relating to clone bd306_7 may be found on pages 37 and 38 of Parent Application 09/197,886 and SEQ ID NO:1 and SEQ ID NO:2 carry the same designation number in the parent

application as well. For this reason, Applicants' assert a priority date of at least the filing date of Application No. 09/197,886, which is November 23, 1998.

In view of a priority date of at least November 23, 1998, the present claims have a priority date which predates Agostino (August 9, 1999) and Jacobs (June 3, 1999). Applicants' therefore submit that the § 102 rejections are improper and should be withdrawn.

The rejection under § 112, second paragraph is over alleged indefiniteness, present in Claims 1(j), 7 and 8. In regards to Claim 1(j), the Office Action finds a lack of clarity due to the fact that polynucleotide in Claim 1(j) cannot encode the same protein as Claim 1(a-i). However, Claim 1 pertains only to polynucleotides. Applicants are unaware of any requirement wherein the claimed polynucleotides must encode the same protein. Consequently, Claim 1 is seen to be in proper form. If this rejection pertaining to Claim 1 is maintained, clarification is respectfully requested.

Claim 8 is also seen to be in proper form, in light of the amendment set forth above. Consequently, withdrawal of the § 112, second paragraph rejections is respectfully requested.

With reference to the rejection under § 101 and the related rejection under § 112, first paragraph. Applicants respectfully submit that the claimed invention has at least one specific and substantial utility and a well-established utility based on the sequence's similarity in sequence to a number of known nucleotide sequences and also based on the predicted protein's similarity to known proteins. In particular, Applicants found similarity between the sequences of the present invention and sequences identified as U47621 (Human nucleolar autoantigen No55 mRNA)(No 55) and X970607 (G. Gallus mRNA for

cartilage associated protein)(CAP) among others. Similarities between the predicted protein of the present invention and the proteins of No55 and the CAP were also found to exist. Based on these similarities, skilled artisans would expect the claimed invention to encode a protein which shares activity with the known proteins. See pages 311 and 312 of the specification. Thus, at the very least, the claimed invention may be used to better characterize these known proteins. This asserted utility is not seen to be a “throw away” utility or a suggestion of further research on the claimed invention. Rather, the asserted utility is for use of the claimed invention as a tool to study other compositions. Furthermore, skilled artisans would be able to use the present invention without a significant amount of further research in applications such as a DNA chip.

As set forth in the utility guidelines published January 5, 2001, a statement of fact made by an applicant in relation to an asserted utility must be treated as true, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. The specification asserts similarities to peptides and proteins and predicts a shared activity. As of yet, the record reflects no evidence that would counter the Applicants’ assertion.

The requirement to accept an applicant’s assertions is not only present in the Utility Guidelines, but also has been recognized in case law. See In re Wright, 27 USPQ2d 1510 (Fed. Cir. 1993).

In response to the asserted similarities, the Office Action asserts that “general statements that a composition that has an unspecified activity or that does not explain why a composition with that activity is believed to be useful fails to set forth a

‘specific utility.’” In support of this position, the Office Action cites Brenner v. Manson, 148 USPQ 689 (Sup. Ct. 1966).

Applicants disagree with such a reading of Brenner v. Manson. In Brenner v. Manson, the Court found a process unpatentable for lack of utility, despite the fact that the applicants in that case produced affidavits revealing an adjacent homologue of the steroid yielded by the claimed process showed tumor inhibiting effects in mice. The Court refused to overturn the Patent Offices finding that the product produced by the process was unlikely to have the same tumor inhibiting effects as the homologue. Nothing in the case indicates that the specification asserted any similarity in activity. Consequently, Brenner v. Manson is not seen to dismiss the importance of an asserted similarity in activity as suggested by the Office Action. In contrast to the application in Brenner v. Manson, the present application goes further than making a reference to an adjacent homologue, the present application has asserted a similarity in activity. Such an assertion which relates to the utility of the present invention, must be taken as true unless there is evidence to the contrary, as discussed above.

Furthermore, Brenner v. Manson was decided in 1966, over three decades ago. Applicants submit that the state of the art has advanced significantly since that time and the state of the art now allows for more accurate predictions.

Applicants also submit that the Office Action has failed to establish a *prima facie* case of lack of utility. The Utility Guidelines published January 5, 2001 set forth the standard for establishing a *prima facie* case for lack of utility. Specifically, the guidelines allow for three different situations which might support a rejection for lack of utility: A) the asserted utility is not specific or substantial; B) the asserted specific and substantial

utility is not credible; or C) no specific and substantial utility is disclosed or is well-established. It is not clear on which one of the three bases the Office Action relies. Regardless, the record fails to establish even one of these bases and therefore the burden of establishing a *prima facie* case for lack of utility has not been met, as explained below.

The most recent Office Action alleges that the present invention is not specific or substantial, leading Applicants to speculate that the rejection might be based on point A). Under point a), a *prima facie* showing of no specific and substantial utility must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. In view of the arguments set forth above and the statements of fact provided in the specification, which Office personnel must treat as true, it is clear that Applicants have asserted a specific and substantial utility and well-established utilities are known to exist based on the similarity to No55 and the CAP. In dismissing, Applicants' assertion of utility, the Office Action has provided no support for factual findings and no evaluation of utilities taught in the closest prior art. Thus, the burden under point A) has not been met and point A) does not apply.

The Office Action mentions the "credibility" of the utility was not assessed, but point B) does not apply.

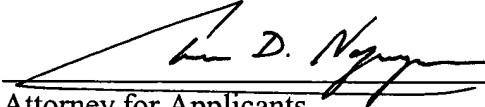
Point C) is also not seen to apply since that point provides for the scenario wherein no utility has been asserted.

In view of the foregoing, Applicants respectfully request withdrawal of the § 101 rejection and the § 112, first paragraph rejection relating to how to make and use the present invention.

With no other matters being raised, the application is seen to be in condition for allowance.

Applicants' undersigned attorney may be reached in our Costa Mesa, California office at (714) 540-8700. All correspondence should continue to be directed to our below-listed address.

Respectfully submitted,



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